

**REMARKS**

Applicants thank Examiner Choi for the courtesies extended during the personal interview held with the Applicants' attorneys on December 15, 2006. The Examiner kindly agreed to consider the present Supplemental Amendment. Interview Summary of December 15, 2006. Applicants have thus amended the independent claims as discussed in the interview to recite "[a] composition consisting of vitamins, minerals and excipients, wherein the vitamins and minerals are combined with each other in an intimate admixture with the excipients." The Examiner indicated that this amendment would overcome prior art rejections.

Claims 232-244 are pending in the application. Claims 1-231 are cancelled. Claims 232-234 have been amended. Support for the amendment of claims 232-234 is found throughout the specification, e.g., paragraphs [0026] – [0050], and particularly paragraphs [0049]-[0054]. It is submitted that no new matter has been introduced by the present amendments, and entry of the both is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

**I. Rejections under 35 U.S.C. § 102(e)**

Claims 187-190, 193, 195, 196 and 198 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bydlon *et al.* (U.S. Pat. Appln. No. 2003/0050341, "Bydlon"). Office Action of May 22, 2006, page 2. Applicants respectfully traverse.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.* Bydlon does not disclose a composition teaching each and every element of the claimed invention.

Claims 187-190, 193, 195, 196 and 198 have been cancelled without prejudice. New independent claims 232-234 recite a composition “consisting of vitamins, minerals and excipients,” in which “iron consists of non-chelated iron in the amount of 50 mg.” Bydlon does not teach a composition of only vitamins, minerals and excipients, where iron is present in this amount. Therefore Bydlon does not teach each and every element of the claimed invention.

Accordingly, Applicants respectfully request that any rejections of claims 187-190, 193, 195, 196 and 198 under 35 U.S.C. § 102(e) over Bydlon be reconsidered and withdrawn, and that claims 232-244 are free of the prior art and in condition for allowance.

## **II. Rejections under 35 U.S.C. § 103**

Claims 187-201 and 217-231 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bydlon *et al.* (U.S. Pat. Pub. No. 2003/0050341, “Bydlon”), in view of Moshhyedi (U.S. Pat. No. 5,770,215, “Moshhyedi”), and one of The Merck Index (pages 892, 893, 1464, 1579, 1580 are provided with the Office Action of May 22, 2006) or Briggs *et al.* (U.S. Pat. No. 4,752,479, “Briggs”). Office Action of May 22, 2006, page 4. Applicants respectfully traverse. Claims 187-201 and 217-231 have been cancelled without prejudice.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Third, the prior art must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999). “The genius of an invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of claims, the law requires

some “teaching, suggestion or reason” to combine the cited references.” *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001).

Claimed ranges must “overlap or lie inside ranges disclosed by the prior art” for a *prima facie* case of obviousness to exist. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Further, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). Additionally, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Bydlon does not teach or suggest a composition consisting of the vitamins specified in the claims, minerals and excipients, where iron is present in the claimed amounts, and Moshyedi, in combination with the Merck Index or Briggs do not make up for this deficiency, moreover, there is no motivation to combine the references, no expectation of success in the combination, and the combination would change the principle of operation of Briggs.

Independent claims 232 and 233 recite a composition “consisting of vitamins, minerals and excipients . . . wherein said vitamins consist of Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, niacin, Vitamin B<sub>1</sub>, Vitamin B<sub>2</sub>, Vitamin B<sub>6</sub>, Vitamin B<sub>12</sub>.” Bydlon relates to a composition containing the fatty acid docosahexaenoic acid (DHA) in combination with at least one vitamin and mineral. Bydlon, abstract. Moshyedi relates to a vitamin supplement containing vitamins and a therapeutically effective amount of a vascular occlusion inhibiting compound, which is preferably aspirin. Moshyedi, abstract. Both Bydlon and Moshyedi therefore require an ingredient in their composition that is not Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, niacin, Vitamin B<sub>1</sub>, Vitamin B<sub>2</sub>, Vitamin B<sub>6</sub>, Vitamin B<sub>12</sub>, a mineral or an excipient. Further, one of ordinary skill in the art would not be motivated to modify either Bydlon or Moshyedi to create the compositions defined in claims 232-244. In either case, such a modification would change the principle of operation of these inventions, and therefore would have no expectation of success.

Independent claims 232, 233 and 234 recite that “iron consists of non-chelated iron in the amount of 50 mg.” The priority document of Bydlon, U.S. Provisional Patent Application

No. 60/318,857, filed September 12, 2001, only relates to a composition containing iron from 14 mg to 42 mg. The amounts of iron recited in claims 232-234 do not overlap or lie inside that recited in Bydlon. U.S. Provisional Patent Application No. 60/318,857, page 9, line 32. Therefore, U.S. Provisional Patent Application No. 60/318,857 cannot be used to make a *prima facie* case of obviousness of the iron ranges recited in independent claims 232, 233 and 234.

Further, Applicants respectfully submit that the Bydlon patent application publication, without priority to U.S. Provisional Patent Application No. 60/318,857, is not prior art to the Applicants' invention. The instant Bydlon patent application publication was filed on September 12, 2002 and published on March 13, 2003. The Declaration Of John A. Giordano Under 37 C.F.R. §1.131 ("the Giordano Declaration") and its associated evidence submitted with the Response filed February 11, 2005, establish that the claimed invention was reduced to practice before May 2, 2002. Therefore, the Bydlon, U.S. Pat. Pub. No. 2003/0050341, is not prior art to the Applicant's application.

The secondary references cited by the Examiner do not make up for this deficiency of Bydlon. Moshyledi does not make up for this deficiency as it relates to iron of at least 5% or 10% of the RDA per unit dose of 6 mg to 30 mg: essentially at least 0.3 mg. Moshyledi, column 7, lines 17-27. Applicants maintain that this range, which is infinite, is so broad as to encompass a very large number of distinct combinations, and thus provides a genus of infinite members which does not render the selection of one species in the genus obvious. The Merck Index, pages 892, 893, 1464, 1579, 1580, do not make up for this deficiency because it does not provide any iron ranges for such compositions.

The Examiner has not provided the requisite "teaching, suggestion or reason" in the prior art that would motivate one of ordinary skill in the art to combine Bydlon, Moshyledi, Briggs and the Merck Index. Moshyledi relates to compositions comprising aspirin and at least one vitamin. Neither Moshyledi, Bydlon, Briggs nor the Merck Index teach or suggest making a nutritional supplement with the amounts of vitamins and minerals disclosed in an aspirin therapeutic for cardiac care patients to be used to supplement the diets of normal pregnant or lactating women, and do not provide an expectation of success in this combination. Further, there would be no motivation or expectation of success to combine Bydlon, Moshyledi and Briggs as they all are tailored to patients with different conditions: the first relates to a nutritional supplement tailored to expectant and new mothers and children,

the second relates to a aspirin-contained cardiac care therapeutic, and the last relates to vitamin supplements for the treatment of anemia. Apparently, it is the Examiner's position that because Bydlon, Moshyedi, Briggs and the Merck Index allegedly suggest "the use of calcium carbonate, magnesium oxide, zinc oxide, copper oxide, thiamine mononitrate, and d,l-alpha-tocopherol acetate in the claimed vitamin and mineral combination, or the amount ranges," one of ordinary skill in the art would be motivated to use these forms of vitamins and minerals, and in the claimed amounts. Office Action mailed May 22, 2006, page 5. However, the mere presence of various forms of vitamins and minerals, and amount ranges in the references of record would not alone motivate one of ordinary skill in the art to make the claimed invention without impermissible hindsight. Further, since the law requires that a "teaching, suggestion or reason" be provided from the prior art, a *prima facie* case for obviousness has not been made.

There is no motivation for one of ordinary skill in the art to combine Bydlon, Moshyedi, Briggs and the Merck Index, nor any expectation of success in the combination. Each reference seeks to solve a different problem in a very crowded area of the art. Moshyedi relates to compositions for therapeutics and vitamin supplementation for cardiac care patients (Moshyedi, abstract), Bydlon relates to compositions for nutritional supplementation for expectant and new mothers and their children (Bydlon, abstract), Briggs relates compositions with improved iron and other divalent ion absorption in patients (Briggs, column 1, lines 52-56), and the Merck Index relates to providing an encyclopedia of chemicals, drugs and biologicals (The Merck Index, title page). Each of these references attempts to solve a different problem, and the Merck Index in particular is in no way attempting to improve the nutrition of pregnant patients. Further, there would be no motivation or expectation of success to combine Bydlon, Moshyedi and Briggs as they all are tailored to patients with different conditions. Finally, the Merck Index teaches away from an expectation of success when it describes the only therapeutic use of magnesium oxide as an "antacid." The Merck Index, pages 892.

Briggs teaches away for the compositions in independent claims 232, 233 and 234, and removes any motivation to combine with Bydlon or Moshyedi. Independent claims 232, 233 and 234 to recite "vitamins and minerals combined with each other in an intimate admixture with the excipients." Briggs relates to dietary supplement formulations that have as their object the ability of the host to absorb iron with maximum efficiency and with

reduced gastrointestinal side effects. Briggs, column 1, lines 52-56. Briggs approaches this object with formulations where the calcium and/or magnesium are in a layer surrounding the iron in order to release them separately in the gastrointestinal tract. Briggs, column 2, lines 11-37 and claim 1. Therefore, one of ordinary skill in the art upon reading Briggs would not be motivated to combine Briggs with Bydlon or Moshyedi to make the composition of the present invention because Briggs teaches away from mixing the calcium and/or magnesium with the iron components, and the compositions of the claimed invention have all of the components of the composition mixed together “in an intimate admixture.” Further, one of skill in the art would also not be motivated to take an iron concentration described in Briggs, which is specifically tailored to the layered, slow release formulation, and apply it to a nutritional supplement without such characteristics and would not have an expectation of success in the combination. Finally, the combination of Briggs with Bydlon or Moshyedi to make the claimed invention of claim would change the principle of operation of the Briggs invention by removing the critical formulatory features, therefore the teachings of these references are not sufficient to render the claims *prima facie* obvious.

Accordingly, Applicants respectfully request that any rejections of claims 187-201 and 217-231 under 35 U.S.C. § 103(a) over Bydlon, in view of Moshyedi and one of the Merck Index or Briggs be reconsidered and withdrawn, and that new claims 232-244 are free of the prior art and in condition for allowance.

### **III. Rejections under Non-Statutory Type Double Patenting**

A. Claims 187-201 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No. 11/296,210. Office Action of May 22, 2006 at page 6. Applicants respectfully traverse.

Claims 187-201 have been cancelled without prejudice. The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting ground. Without addressing the propriety of the Examiner’s rejection, and specifically the Examiner’s interpretation of what the cited references teach or suggest, Applicants respectfully and properly defer addressing the present rejection until there is otherwise allowable subject matter in the present application. Only then is it proper to assess the propriety of the

Examiner's rejection in view of the potentially allowable claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections or that the rejections be held in abeyance until claims 232-244 are allowable in the present application.

**B.** Claims 187-201 and 217-231 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No. 11/296,210. Office Action of May 22, 2006 at page 7. Applicants respectfully traverse.


Claims 187-201 and 217-231 have been cancelled without prejudice. The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting ground. Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully and properly defer addressing the present rejection until there is otherwise allowable subject matter in the present application. Only then is it proper to assess the propriety of the Examiner's rejection in view of the potentially allowable claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections or that the rejections be held in abeyance until claims 232-244 are allowable in the present application.

**CONCLUSION**

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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